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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,695	02/22/2002	James F. McGuckin JR.	1917	1281
7590	02/11/2004		EXAMINER	
			DESANTO, MATTHEW F	
			ART UNIT	PAPER NUMBER
			3763	11
DATE MAILED: 02/11/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/081,695	MCGUCKIN ET AL.
	Examiner	Art Unit
	Matthew F DeSanto	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 November 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14,27 and 31-38 is/are pending in the application.
- 4a) Of the above claim(s) 37 and 38 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-14,27 and 31-36 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 37, 38 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: drawn to a non-elected species. See paper number 6 and 7.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 37, 38 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "flexible member formed by a cutout."

Claim Objections

3. Claim 1 is objected to because of the following informalities: The term "retention member" is never positively recited; the term is only inferential included because "retention member" is incorporated in the functional language of the actuator. To gain the structure of the retention member, please positively recite it. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The "flexible member formed by a cutout" cannot be found in the specification and the applicant does not give information to where that limitation is in the specification.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Hofling (5,419,777).

Hofling discloses a surgical apparatus surgical apparatus for delivering fluid to treat a lesion comprising an elongated member having a distal tip and a plurality of openings formed in a sidewall proximal of the distal tip; a plurality of fluid delivery

members movably positioned in the elongated member, each of the fluid delivery members having a lumen and at least one opening communicating with the lumen for delivering fluid to the lesion; and an actuator operatively associated with the fluid delivery members, and a first tube (24) [Column 6, lines 47-55] and wherein the actuator (56) actuatable to a first position to move the fluid delivery members from a retracted position within the elongated member to a first deployed position extending radially with respect to the elongated member and actuatable to a second position to move the fluid delivery members from the first deployed position to a second deployed position extending further radially from the elongated member, the fluid delivery members being retained in the first and second deployed positions by a retention member (62) (See Figure 5, Column 6, lines 14-65 and entire reference).

8. Claims 27, 35, 36 are rejected under 35 U.S.C. 102(e) as being anticipated by McGuckin et al. (USPN 6,425,887).

McGuckin et al. discloses a surgical apparatus surgical apparatus for delivering fluid to treat a lesion comprising an elongated member having a distal tip and a plurality of openings formed in a sidewall proximal of the distal tip; a plurality of fluid delivery members movably positioned in the elongated member, each of the fluid delivery members having a lumen and at least one opening communicating with the lumen for delivering fluid to the lesion; and an actuator operatively associated with the fluid delivery members, and a first tube (56) [Column 6, lines 47-55] and wherein the actuator (79) actuatable to a first position to move the fluid delivery members from a retracted position within the elongated member to a first deployed position extending radially with

respect to the elongated member and actuatable to a second position to move the fluid delivery members from the first deployed position to a second deployed position extending further radially from the elongated member, the fluid delivery members being retained in the first and second deployed positions by a retention member (See Figure 21, 22, Column 11, lines 24-38 and entire reference).

9. Claims 1, 4, 5, 6, 7, 12, 13, 14, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Flaherty et al. (USPN 6,283,951).

Flaherty et al. discloses a surgical apparatus surgical apparatus for delivering fluid to treat a lesion comprising an elongated member having a distal tip and a plurality of openings formed in a sidewall proximal of the distal tip; a plurality of fluid delivery members movably positioned in the elongated member, each of the fluid delivery members having a lumen and at least one opening communicating with the lumen for delivering fluid to the lesion; and an actuator operatively associated with the fluid delivery members, and a first tube (62) and wherein the actuator (68) actuatable to a first position to move the fluid delivery members from a retracted position within the elongated member to a first deployed position extending radially with respect to the elongated member and actuatable to a second position to move the fluid delivery members from the first deployed position to a second deployed position extending further radially from the elongated member, the fluid delivery members being retained in the first and second deployed positions by a retention member (70) (See Figure 1A-1E, 5B, and entire reference).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1, 4, 5, 6, 7, 8, 9, 12, 13, 14, and 31, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofling (USPN 5,419,777) as applied to the claims above, and further in view of Flaherty et al.

Hofling discloses a surgical apparatus with a plurality of fluid delivery members, an actuator (56) and a retention member (62), but fails to disclose wherein the fluid delivery members have more than one aperture. (See Figure 5, Column 6, lines 14-65 and entire reference).

Flaherty et al. disclose a similar device and wherein the fluid delivery members have a plurality of apertures depending on the intended use of the medical apparatus. (Column 10, lines 61-67)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the references of Hofling and Flaherty et al. because Flaherty et al. discloses reasons for using multiple openings in the fluid delivery member, therefore it would be useful to have many openings when delivering fluid to radial area.

12. Claims 1-9, 12-14 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin et al. as applied to above, and further in view of Flaherty et al.

McGuckin et al. discloses a surgical apparatus with a plurality of fluid delivery members, an actuator and a retention member, but fails to disclose wherein the fluid delivery members have more than one aperture.

Flaherty et al. disclose a similar device and wherein the fluid delivery members have a plurality of apertures depending on the intended use of the medical apparatus. (Column 10, lines 61-67)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the references of McGuckin et al. and Flaherty et al. because Flaherty et al. discloses reasons for using multiple openings in the fluid delivery member, therefore it would be useful to have many openings when delivering fluid to radial area.

13. Claims 1-14, 27, 31-32, 34, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin et al. in view of Flaherty et al. as applied above, and further in view of Foster (USPN 6,217,559).

McGuckin et al discloses the claimed invention except for the retention member comprising a tab mounted on the actuator in one of the plurality of recesses formed in the housing.

Foster teaches a tab mounted on the actuator in one of the plurality of recesses formed in the housing (See Figure 1-4 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of McGuckin with the teachings of the locking device of Foster because Foster teaches an efficient and effective locking mechanism on a

surgical device which allows for the "needle" to be maintain in a deployed position and then released when necessary, (Foster Columns 1 and 2), as well as an obvious modification to have two tabs instead of one. This would be a duplication of parts. Duplicating the components of a prior art device is a design consideration within the skill of the art. In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-14, 27, and 31-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the copending Application No. 10/074468, and 10/145,863. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim similar structure such as an actuator, pluralities of needles, and retention member.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

16. Applicant's arguments with respect to claims 1-14, 27, 31-38 have been considered but are moot in view of the new ground(s) of rejection.
17. The 102 Rejection in view of Edwards et al. has been withdrawn.
18. With regards to the McGuckin et al. reference and claim 27, the reference teaches the claimed invention in Column 10, lines 1-13.
19. With regards to the first and second deployed positions, the examiner interprets this language to be functional and thus the prior art of record is capable of performing that function. The retention member, the actuator and the medical technical perform the function therefore, the prior art still reads on the claim.
20. The examiner has some suggestions that might speed up prosecution and overcome the prior art.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto
Art Unit 3763
February 6, 2004



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